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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,870	04/17/2001	Claude Jarkae Jensen	10209.166	5882

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EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/836,870

Applicant(s)

JENSEN ET AL.

Examin r

Gina C. Yu

Art Unit

1617

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period f r R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2002 has been entered. Claims 1, 2, and 4-28 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 4-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification and prior art do not enable using a quantity of Proxeronase to active a release of Xeronine. The specification and prior art do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim without undue experimentation.

Factors to be considered in determining whether any necessary experimentation is “undue” include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

Applicants’ disclosure fails to enable the claimed method of “using a quantity of Proxeronase to active a release of Xeronine” because there is no guidance either in the specification or in prior art for a skilled artisan to define or obtain such quantity of Proxeronase. It is further not clear what applicants mean by “using” Proxeronase, since applicants’ disclosure and prior art indicate that Proxeronase is inherently present in the fruit juice of noni. See rejection under 35 U.S.C. § 112, second paragraph below. Undue experimentation is necessary to determine what is the quantity of Proxeronase which activates a release of Xeronine and how to use the invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 4-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “providing” used in claim 1, lines 1 and 3, renders the claim vague and indefinite. The only reasonable interpretation of the term “providing” used in line 1 is

“making”, as in the context of a method claim. Using the same term in line 3 however renders the scope of the claim indefinite because the claimed method appears to involve a method step of “making” pure noni juice, which is not defined or explained by the specification.

The term “pure” also is vague and indefinite as it is a relative term. The term “pure” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term “using” in claim 1, line 7 also renders the claim vague and indefinite. Prior art and applicants’ disclosure indicate that Proxeronase is inherently present in the fruit juice of noni. The scope of the claim is unclear, as the method step appears to involve some physical steps of “using” the compound, while it is known in the art that the compound is inherently present in the composition and therefore activates the release of Xeronine from Proxeronine as a natural reaction. See specification, p. 22, lines 11 – 23; instant claim 2.

The terms “PEG-115M”, “FD & C Blue No.1”, and “FD & C Yellow No. 5” in claim 19; and the terms “SD alcohol 40-B”, “PG”, “Ext. Violet 2” and “green 2” in claim 24 appear to be trademarks, which should not be recited in patent claims. A trademark or tradename is used to identify a source of goods, and not the goods themselves. If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the § 112, second paragraph. See MPEP 2173.04(u). The scope of the claim is uncertain

since the trademark or trade name cannot be used properly to identify any particular material or product. Furthermore, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

1. The instant claims recite the method steps of combining noni fruit juice with a physiologically acceptable vehicle, which have been practiced in public according to Moniz (US 52288491). Moniz teaches that noni juice diluted with water has been used as ancient folk medicine in the Pacific. See col. 1, line 40 – col. 2, line 65. The making of diluted juice composition by combining noni fruit juice with water, a cosmetically suitable carrier, meets the instant claim limitation. The presence of Proxeronine and “the inactive form of enzyme which releases xeronine from Proxeronine”, which is viewed as Proxeronase, in the noni fruit juice is inherent. See Moniz, col. 3, lines 1 – 18. Examiner takes the position that the phrase “topical cosmetic skin toner composition designed to hydrate and balance pH levels in said skin” in claim 1 is a mere preamble statements reciting purpose or intended use of a composition made by the method steps known in public, and not a claim limitation. It is well settled patent law that, if the body of a claim fully and intrinsically sets forth all of the limitations of the

claimed invention, and the preamble merely states the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitation, then the preamble is not considered a limitation and is of no significance to claim construction. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F. 3d 1298, 1305, 51 U.S.P.Q. 2d 1161, 1165 (Fed. Cir. 1999). It is also held that if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See *In re Schreiber* 128 F.3d 1473, 1477, 44 U.S.P.Q. 2d 1429, 1431 (Fed. Cir. 1997). See also MPEP 2112.02. In this case, the only structural limitation in claim 1 is combining noni fruit juice and a cosmetically acceptable medium, which, according to *Moniz*, has been practiced by public.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Nonidrink.com advertisement (www.nonidrink.com/skin_care.html), "Tahitian noni juice information about noni juice", copyrighted 1998-1999) in view of *Moniz*.

Nonidrink.com indicates that Tahitian Noni skin care system, "like all of Morinda's products it has been developed around . . . Tahitian Noni juice." See www.nonidrink.com/skin_care.html, "Tahitian noni juice information noni juice", copyrighted 1998-1999. While there is no explicit mention that the disclosed products are used as a "toner", examiner views that the recited term "toner" in the instant claim

indicates an intended use or purposes and not a structure limitation of the claimed method.

While the Nonidrink.com advertisement fails to disclose the weight amount of noni juice present in the Tahitian noni cosmetic products, differences in concentration in general will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05.

Moniz teaches that the presence of Proxeronine and Proxeronase in the composition is inherent. See col. 3, lines 1-18.

Given the teaching that Tahitian noni juice is added to cosmetic compositions examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. It would have been obvious to the skilled worker that varying the concentration would depend on factors such as enhancing the effects of noni juice or cost efficiency.

2. Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Nonidrink.com advertisement and Moniz as applied to claims 1,2, and 4-17 above, and further in view of Duffy et al. (US 5472699).

The combined references fail to disclose the additional ingredients recited in instant claims 18-28.

Duffy teaches a cosmetic composition comprising botanical astringent comprising extracts from Witch Hazel, Linden which is a source of vitamin C, E, and farnesol, and St. John's Wort which is a source of vitamin A. Employing silica, water, ethyl alcohol (denatured alcohol), glycerin, pyridoxine HCL, fragrances, thickeners, preservatives,

and colorants are also disclosed. See the formula on col. 6, lines 35 – 45 for instant claim 18. The Duffy patent teaches that the invention helps reduce the size of pore of the skin and control sebum secretion.

Given the general teaching of making cosmetic compositions from noni fruit juice in the combined references, one of ordinary skill in the art at the time the invention would have been motivated to look to prior arts such as Duffy for specific additive components suitable for botanical astringents and combined the ingredients because of the expectation of successfully producing a noni juice skin care composition that improves skin appearance by reducing the pore size and controlling oil secretion.

Response to Arguments

Applicant's arguments with respect to claims 1,2, and 4-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
November 12, 2002



SREENI PADMANABHAN
PRIMARY EXAMINER

11/16/02